USER'S MANUAL









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	conformance with the User's Manual.

Revisions

The list of revisions below summarizes replacements or additional pages in your User's Manual.

Version	Date of printing	Modifications	Pages modified
А	09/2008	Creation	All
В	03/2009	Addendum # 4501-1842 insert	P 2-6

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Note: Screenshots, figures, and messages are given for information purposes only.

1. How to use this manual

This manual provides the appropriate instructions to install, operate and maintain the **PREVI™ Color Gram** instrument.

Warnings

Different types of warnings are used throughout the manual:

- for safety reasons (DANGER!),
- to ensure that the instruments are maintained in good working condition (CAUTION!),
- for regulatory reasons (WARNING!) or,
- for optimum performance of operations, procedures, etc. (IMPORTANT!).

Before using your instrument, please also read the "General safety and regulatory information" booklet, provided with the instrument, and the above mentioned warnings.

Specific warnings



DANGER!

The PREVI™ Color Gram must be installed in a well ventilated area.

If power is lost while the stainer is running, do not open the lid until carousel rotation ceases. Check the amber rotation light on the front panel and listen for the sound of carousel rotation to cease.

The anhydrous alcohol used in the instrument is highly flammable. A break or malfunction in the reagent delivery system has the potential of releasing up to 500 ml of alcohol in and around the instrument. If this occurs, carefully shut off the power to the stainer and consult the safety sheet for information in handling alcohol spills. Do not use the instrument again until any leaks are repaired.

Regarding the PREVITM Color Cytocentrifuge Rotor, lid and rotor gaskets and related components are intended to be part of biosafety systems such as are specified in international and national biosafety guidelines, and cannot be relied on as the only means of safeguarding workers and the environment when handling pathogenic micro-organisms.

bioMérieux recommends distilled water for reagent D and ethanol for reagent E. Methanol can also be used for reagent E, nevertheless its use is subject to specific safety precautions and requires the instrument to be placed under a safety hood.

CAUTION!

To avoid serious instrument damage, never use reagents other than those supplied by bioMérieux.

Except for both reagent mentioned above, using reagents not supplied by bioMérieux may seriously damage the stainer and may void your warranty.

IMPORTANT!

Please read this manual carefully before using the PREVI™ Color Gram. In all cases of maintenance and repair, work should only be undertaken by a skilled technician. Untrained personnel should not attempt to dismantle the instrument.

Only spare parts supplied or specified by bioMérieux should be used. Fitting of non-approved parts may affect the performance and safety features designed into the instrument.

If the equipment is used in a manner not specified in the instructions for use provided by bioMérieux, the protection provided by the equipment may be impaired.

If in doubt, contact your bioMérieux representative.

2. General

Functional description

The PREVI™ Color Gram is designed to Gram stain specimen smears on microscope slides.

A Gram stain aids in the presumptive diagnosis of the illness, and it gives preliminary classification of the causative agent.

This microprocessor-controlled slide stainer is dual purpose. Additionally, the *PREVI™ Color Cytocentrifuge Rotor* allows to quickly sediment sample cells onto microscope slides for staining or other purposes.

The chemical mechanism of Gram differentiation is based on the differential cell wall permeability to the Crystal Violet-Iodine complex. The Gram stain yields a specimen in which the Gram-positive organisms are purple to black and the Gram-negative organisms are pink to red.

Key features

PREVI™ Color Gram's features are:

- · minimized reagent consumption
- · fast staining
- high volume staining productivity (12 or 30 slides at a time)
- CLEAN cycle to purge each spray nozzle with ethanol or methanol
- 9 operator-selected decolorizer cycles*
- · separate reservoir, delivery tube, pump and spray nozzle for each reagent
- operator-selectable ethanol or methanol fixation function to fix samples.

The correct accessory must be used for each function.

The *PREVI™ Color Cytocentrifuge Rotor* is available from bioMérieux as an option offering additional features.

* program no. 2 and 3 recommended by bioMérieux.

Intended use

The **PREVI™ Color Gram** is an *in vitro* diagnostic medical device for professional use only.

The **PREVITM** Color **Gram** has been designed to perform automated Gram staining of human sample micro-organisms for *in vitro* diagnostics with bioMérieux reagents only.

The **PREVI™ Color Gram** has been qualified with the following cell suspensions:

- blood
- bronchoalveolar liquid (BAL)
- · cerebrospinal fluid (CSF)
- feces
- sputum
- · vaginal swab
- urine.

WARNING!

bioMérieux disclaims any responsibility for the use of the PREVI™ Color Gram with biological cell suspensions other than those mentioned above.

Specifications

General

PARAMETERS	CHARACTERISTICS
Main power input	100 − 240 V~ / 50 - 60 Hz The power setting is indicated on the back panel.
Power Consumption	85 W max
Fuse rating	2A-250V ~ IEC TYPE T 5x20 mm (0.2x7.9 inches)
Outside dimensions Width Depth Height - Lid open Height - Lid closed	560 mm (22 inches) 530 mm (21 inches) 580 mm (23 inches) 240 mm (9.5 inches)
Weight	16.8 kg (37 lbs)
Ambient temperature Operation Storage	15 °C to 30 °C (59 °F to 95 °F) - 20 °C to 60 °C (- 4 °F to 140 °F)
Relative humidity	maximum 80% at up to 31 °C
Altitude	≤ 2000 m
Pollution degree	2
Over-voltage category	II

Performance

PARAMETERS	CHARACTERISTICS
Reagent spray nozzles	Each reagent has a separate spray nozzle to dispense the correct amount of reagent.
Reagent channel	 A - Fuchsin or Safranin (with or without acetone) B - Iodine C - Crystal Violet D - Distilled water * E - Ethanol or methanol **
Carousel capacity	12 slides 30 slides
Run	9 operator-selected decolorizer cycles (Program no.2 and no.3 validated by bioMérieux)
Rotor speeds	20 rpm for staining (rpm - revolutions per minute) 950 rpm for drying

^{*} Not provided by bioMerieux. Since distilled water and ethanol or methanol are not available from bioMérieux, it must be obtained locally. Water should be filtered (0.2 micron inline filter) to remove bacteria and particulates.

^{**} Ethanol or methanol should be 99.8% pure.

Run timing sequence and reagent consumption - General references

The following table includes the general references for a staining cycle at DECOLORIZER 3.

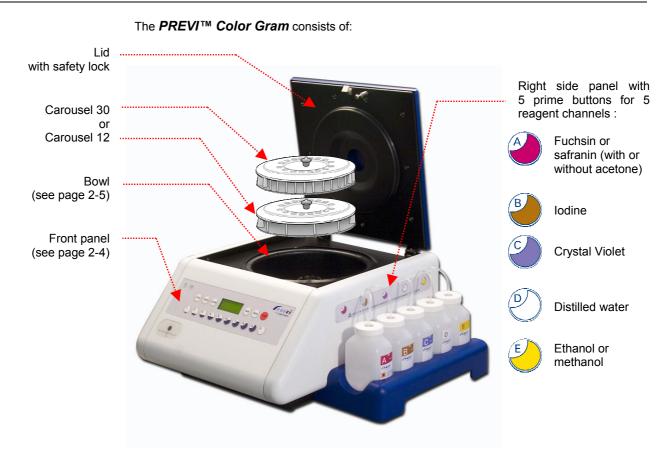
Phases			Slides carousel			
		PUMP	12		30	
			Time sec	Volume ml	Time sec	Volume ml
(0)	FIXATION*	(E)	(70)	(3.0)	(82)	(3.5)
1	CRYSTAL VIOLET	С	35	4.5	43	5.5
2	WASH	D	25	17.3	34	23.5
3	IODINE	В	30	4.5	38	5.7
4	WASH	D	33	22.8	69	47.8
5	DECOLORIZER	Α	39	6.0	47	7.2
6	WASH	D	20	13.8	34	23.5
7	HIGH SPEED DRY	-	55	-	55	-
Total without alcohol fixation		237 4 min	69	320 5.3 min	113.3	
	Total with alcohol fixation			144	402 6.7 min	116.8

^{*} Option for ethanol or methanol fixation.

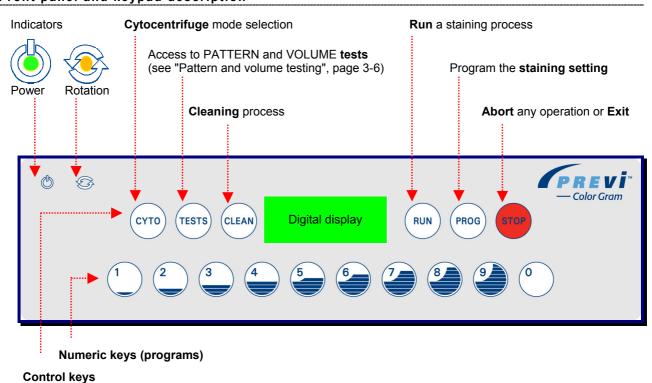
References

PRODUCTS	REFERENCES
PREVI™Color Gram CD Rom PREVI™Color Gram User's Manual	
PREVI™Color Cytocentrifuge Rotor User's Manual	
General Safety and Regulatory Information	
fr, en, de, es, it, pt, el, sv, da, pl, hu, sket, lt, lv, ru, ja, tr, na, zh, ko, th	
REAGENTS	
 Acetone safranin-A Safranin-A Acetone fuchsin-A Fuchsin-A lodine-B Crystal violet-C 	See your bioMérieux
Nozzles * 2	representative
Nozzle o-ring	
Nozzle wire	
Nozzle cleaning solution	
Slide carousel: 12 / 30	
D&E empty bottle	
D&E 5-Liter empty bottle	
Waste tubing	
Waste container	
Maintenance kit	

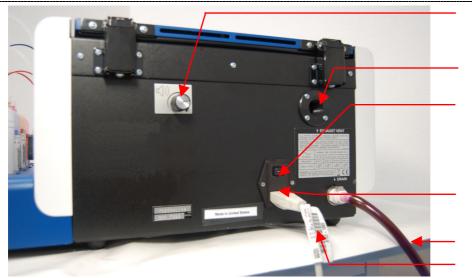
Description



Front panel and keypad description



Back panel



Volume button:



(signal tone setting)

Exhaust vent

Power switch:





Fuse door; alternative (see "Specifications", page 2-2).

Waste tubing

Power cord

Bowl



Spray nozzle orifices:

D_R - Distilled water Rear

E - Ethanol or methanol

C - Crystal Violet

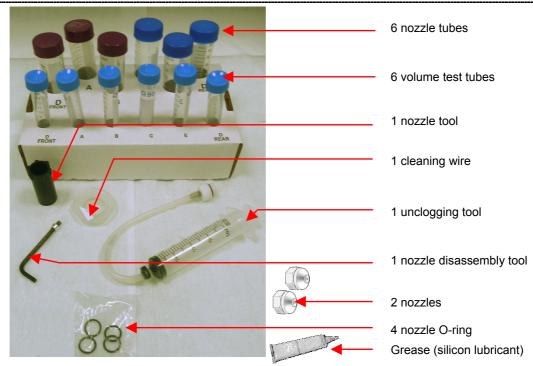
B - Iodine

A -- Fuchsin or Safranin (with / without acetone)

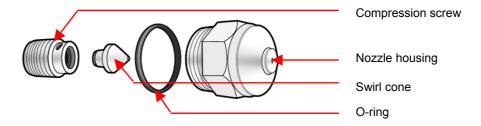
D_F - Distilled water Front

Drive hub

Maintenance kit



Nozzle



Nozzle cleaning solution

The nozzle cleaning solution is used for the *PREVI™ Color Gram* maintenance operations.

The 2.5 L concentrated nozzle cleaning solution (reference 29525) is contained in a 5-liter bottle. The concentrate is composed of 25.2 g of Oxalic Acid Dihydrate per liter of deionized

It contains at least 1% of Oxalic Acid Dihydrate (the Material Safety Data sheet is available on request).

The nozzle cleaning solution must be reconstituted before use by adding 2.5 liters of ethanol (C₂H₆O) or methanol (CH₄O) (99.8%) to the 5 L bottle.

This instruction is symbolized on the bottle label by the following mention:

"--> + 2.5 L (C_2H_6O or CH_4O)".

The reagents required but not provided (ethanol or methanol) may present a chemical risk and should be handled with care. Reconstituted Nozzle Cleaning Solution with ethanol or methanol, can be hazardous and should be handled with the same care.

The concentrated nozzle cleaning solution must be stored at 15-25°C until the expiry date indicated on the bottle label.

After reconstitution, the solution must be stored at 15-25°C until the expiry date.

For practical reasons, the solution can be transferred into a 500 mL or a 1-liter bottle. In this case, it is important to record the expiry date on the bottle. Please refer to "Maintenance and cleaning" section, page 5-4.

Waste disposal: the Nozzle Cleaning Solution effluents must be treated in the same manner as the reagents, see warning page 5-3.

Note: The nozzle cleaning solution is available separately.

Please contact your bioMérieux representative.

Other parts

Since the following parts are not available from bioMérieux, they must be obtained locally:

- ethanol or methanol more than 99.8 % pure
- distilled water.

Empty bottles can be provided by bioMérieux (see "References", page 2-3).

WARNING!

ETHANOL OR METHANOL are not provided by bioMérieux. The customer should purchase them locally and observe the recommendations, in terms of safety and chemical risk.



3. Installing the PREVI™ Color Gram

CAUTION!

If you observe any damage on the packaging or equipment, please contact your bioMérieux representative before installing the instrument.

Place the instrument with at least 30 cm (12 inches) clearance from obstructions or hazardous materials.

Unpacking procedure



Open the 2 boxes and remove the protection (foam packaging).



Check the contents according to the packing lists included in the 2 boxes (instrument and accessories).



Lift the stainer out of the box.



Place the instrument on a flat surface, free from dust and vibration and away from direct sunlight.





Installation procedure

CAUTION!

Ensure that the distance between the back panel of the PREVI™Color Gram and the wall is at least 30 cm (12 inches).

Before the PREVITM Color Gram is installed and switched ON it should be left to stand for at least three hours so that there is no possibility of condensation causing a hazardous situation.

Keep the waste container tube straight and as short as possible: 2 meters (79 inches) maximum.

The waste container tube should be positioned at a lower level than the table. If possible, bioMérieux recommends you to install the instrument at an extremity of the bench top.

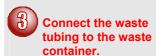
Installing waste tubing



Clip the waste tubing into the *PREVI™Color Gram* and push until you hear a "click".







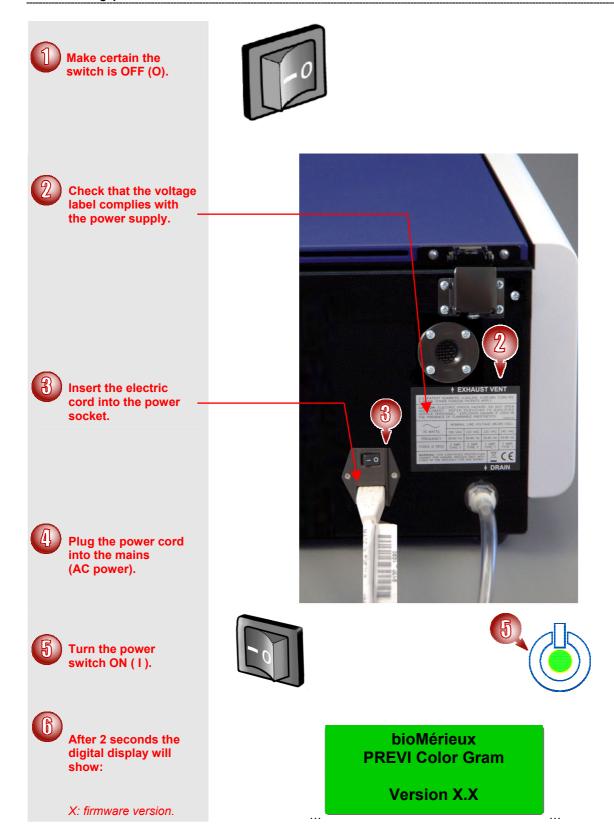
Drip tray ..







Connecting power



Installing reagent bottles



DANGER!

Reagents used in the PREVI™ Color Gram contain moderately hazardous chemicals that require care in handling. Always use appropriate safety measures including gloves and eye protection when handling reagents.









Fill the E bottle with ethanol or methanol 99.8% pure and the D bottle with distilled water.



Place each bottle in the appropriate position.



Open the new bottle, record the letter on the cap and keep it for future use (e.g. long term storage).



Insert the dip tube "E" into the reagent bottle "E" and screw on the ring cap.



Repeat step 3 for bottles D,C,B,A.

Note: For frequent use 5-L bottles D & E are available, see "References" page 2-3. To install the bottles, cut the tubing just above the dip tube. Install the bottles in a drip tray.







Right side panel with 5 prime buttons for 5 reagent channels:



Fuchsin or Safranin (with or without acetone)



lodine



Crystal Violet

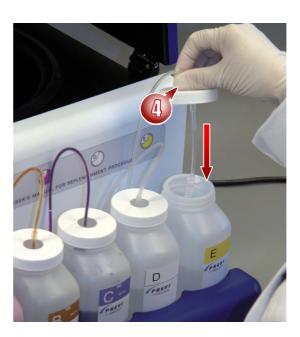


Distilled water



Ethanol or methanol





Preparation procedure

IMPORTANT! To obtain optimum performance, thoroughly purge and prime each reagent

delivery line using the following instructions.

CAUTION! This procedure must be applied before the 1st use of the instrument.

WARNING! Never operate a dry pump for more than 10 seconds.

Nozzle checking

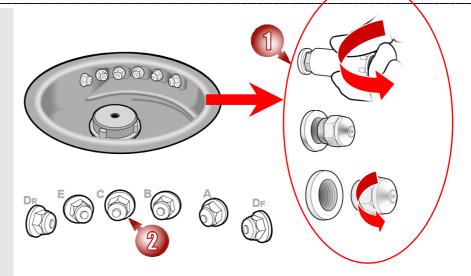


Remove each spray nozzle with the nozzle tool by turning the counter clockwise.





Note the location of each nozzle so you can return it to the original location.





Hold a sheet of white paper in front of the nozzle A.



Press and hold each prime button.



Stain should appear within 5 seconds.

If this is the case: go to step 6.

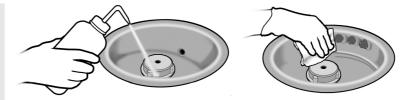
If not, immediately stop the procedure and see "Unclogging the tubing", page 5-8.





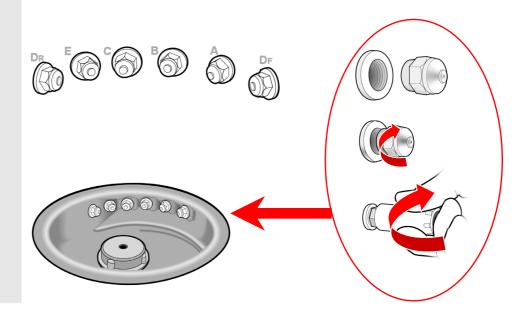


Flush with distilled water and wipe dry the bowl and the nozzles.





Replace each spray nozzle by hand and then with the nozzle tool by turning clockwise.



Pattern and volume testing

For first use, please refer to both of the following tests:



The "Pattern test", page 4-3

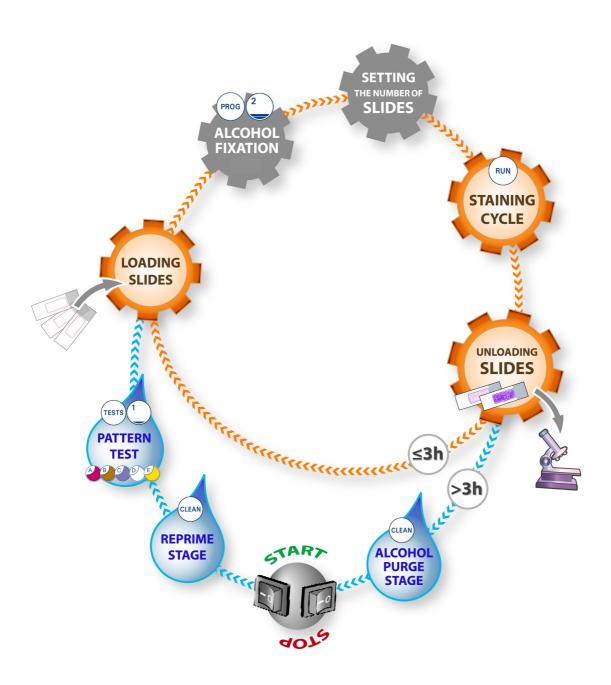


Then the "Volume test", page 5-10.

IMPORTANT! After this p

After this preparation procedure, follow the ROUTINE use described in "Operating the PREVITM Color Gram", page 4-1.

4. Operating the PREVI™ Color Gram



PREVI™ Color Gram routine process

Key

Orange line: run process

Blue line: maintenance process

Grey elements: optional part

This routine process flow diagram describes the necessary stages for the routine use of the instrument. Details are given in the following sections.

CAUTION!

The reagent AND waste liquid levels must be monitored by the user.

To ensure proper staining and to protect the instrument, never allow:



- a reagent line to run dry. When the reagent liquid level is near the bottom of a reagent bottle, replace the bottle, see "Replacing a reagent bottle", page 4-12.

- the waste liquid level to be above the maximum safety level. When the waste container is full, empty it. See "Emptying the waste container", page 4-13.

IMPORTANT!

To obtain optimum performance, thoroughly purge and prime each reagent delivery line using the following instructions.

WARNING!

Never operate a dry pump for more than 10 seconds.



The CLEAN cycle is a two-stage process that re-primes reagents into the nozzles then uses ethanol or methanol 99.8% pure to purge the reagent nozzles of precipitates and debris.

CLEAN reprime stage

IMPORTANT!

If you have not used the PREVI™ Color Gram before, go directly to "Installing reagent bottles", page 3-4.

This stage must be completed before restarting several runs to complete the CLEAN cycle.

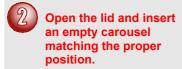


The CLEAN reprime stage requires the use of 7.5 ml of A, B, C reagents (Alcohol, Iodine, Crystal Violet) and 10 ml of reagent D (Distilled Water) divided equally between each nozzle.

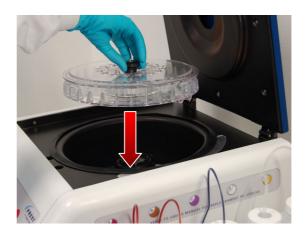


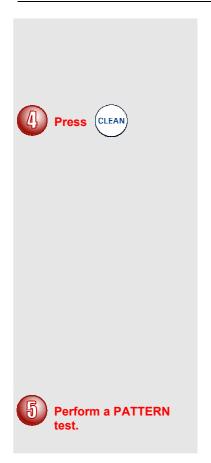


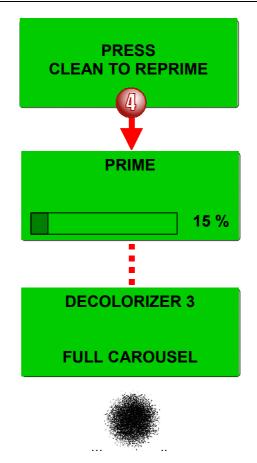








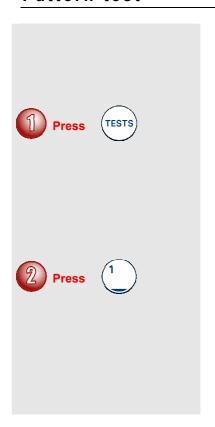


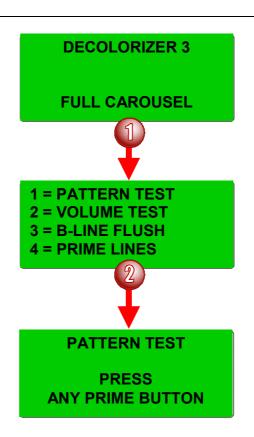


Note: If a

If a CLEAN cycle is aborted, a warning message will be displayed until the CLEAN cycle is completed.

Pattern test







Hold a sheet of white paper in front of nozzle A.













Check the quality of the pattern.

If the pattern is not correct, see "Nozzle handling", page 5-4.









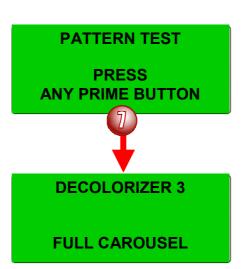


Repeat steps 3, 4 and 5 for all the other nozzles (D_F, D_R, B, C and E)



Press





Loading slides

CAUTION!

Never load chipped or cracked slides into the instrument. Failure to use slides in good condition can lead to breakage during the staining cycle. If slides do break in the bowl, see "Cleaning", page 5-18.

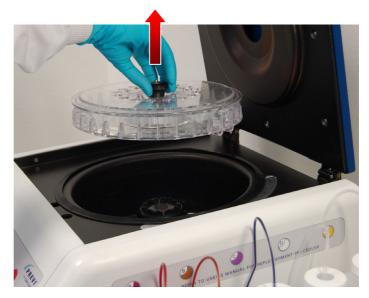
Make certain there are no small ferrous metal objects on the lab bench. These can be attracted to the magnets on the bottom of the carousel and cause damage if spun free of the magnets during spinning of the carousel.

Slides must be loaded in balanced pairs. If an odd number of slides need to be stained, use a blank slide.

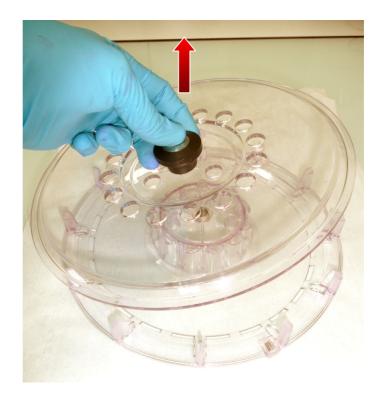
IMPORTANT!

Carousels must be loaded with similar specimens for a similar level of staining. Otherwise bioMérieux does not guarantee the staining performance.





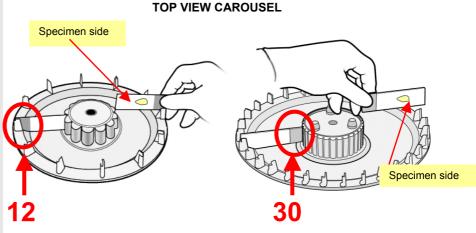






Insert the slides into the carousel.

The slides must be inserted diametrically opposite one to the other to balance the carousel.





Be sure that slides

If an odd number of

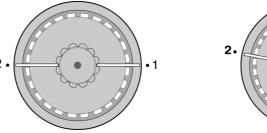
slides need to be stained, use a blank

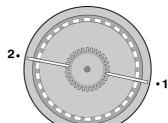
are loaded in balanced pairs.

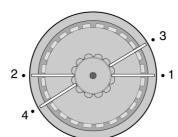
slide.

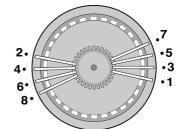


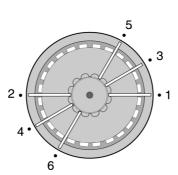
Label: toward the center

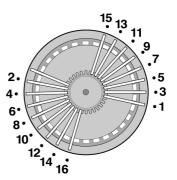


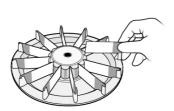


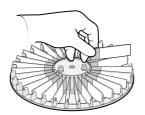












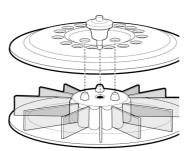
CAUTION!



A signal tone sounds during the run if the position of the slides is unbalanced.



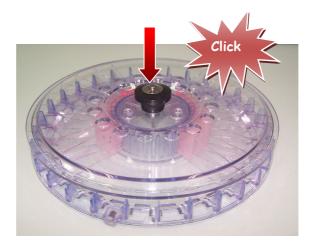
Replace the lid by pressing the button and lowering the lid over the indexing posts.







Release the button and press the lid handle until it clicks into place.





Place the carousel in the bowl and close the lid.



Starting a staining cycle

CAUTION!

A new cleaning cycle should be performed if the time between runs exceeds 3

The reagent and waste liquid level must be monitored by the user.

To ensure proper staining and to protect the stainer:

- never allow a reagent line to run dry. When the reagent liquid level is near the bottom of a reagent bottle, replace the bottle, see "Replacing a reagent bottle", page 4-12.

- never allow the waste liquid level to go above the maximum safety level. When the waste container is full, empty it: see "Emptying the waste container", page 4-13.

WARNING!

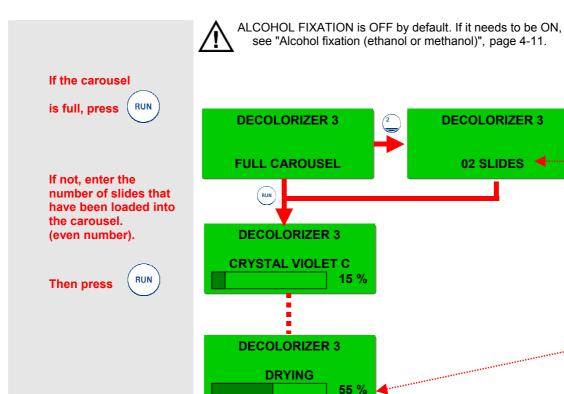
bioMérieux recommends the use of the default DECOLORIZER setting.

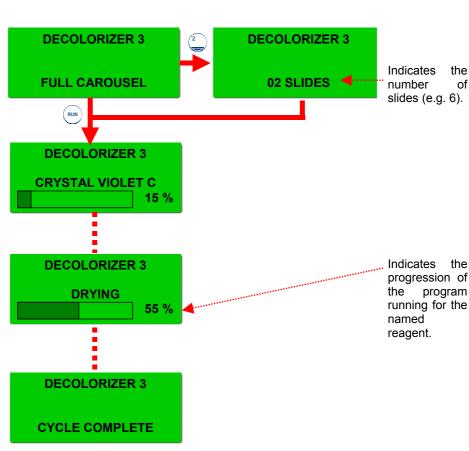
IMPORTANT!

as an emergency stop when required (e.g. abnormal vibration or

see "Alcohol fixation (ethanol or methanol)", page 4-11.

noise): the staining cycle will be aborted.





CAUTION!

A signal tone sounds at the end of the cycle.

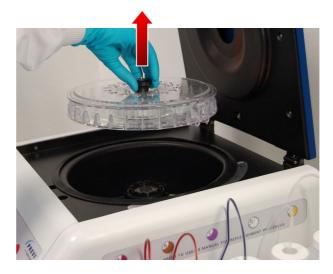
Unloading slides

WARNING!

Treat slides in accordance with good laboratory practice guidelines and local regulations.



Remove the carousel from the bowl.



Remove the carousel lid by pressing the button and lifting the lid away.



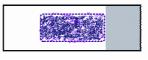
Carefully remove each slide already dried and read the Gram results with a microscope.





Negative-Gram





Positive-Gram



CLEAN alcohol purge stage

CAUTION!

The CLEAN cycle must be used each time the PREVI™ Color Gram is left on stand-by FOR MORE THAN 3 HOURS.

The alcohol purge stage must be performed after each staining period and the prime stage must be performed just before restarting the instrument.



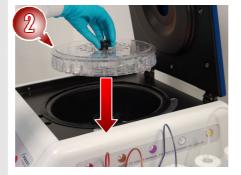
This stage requires the use of 10 ml of alcohol divided equally between each



Be sure the stainer light is ON.



Place the empty carousel in the instrument and close the lid.



DECOLORIZER 3

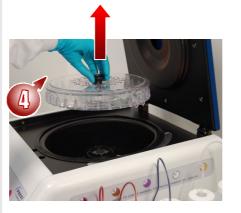




Press (CLEAN



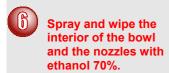
Open the lid and remove the carousel.



PRESS CLEAN TO REPRIME







4-10





IMPORTANT!

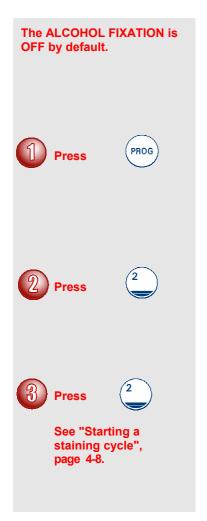
After this first cleaning stage, if the instrument remains on stand-by for more than one week, please refer to the "Long-term storage", page 5-16.

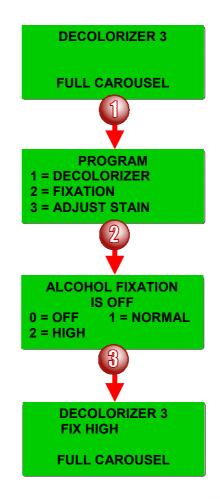
Alcohol fixation (ethanol or methanol)

Automated fixation can be used in place of manual fixation.

WARNING!

bioMérieux strongly recommends the use of the HIGH fixation mode and not the NORMAL mode. ALCOHOL fixation in normal mode is shorter and may lead to specimen loss.





Note:

The ALCOHOL fixation can be deactivated by pressing above procedure.

in step 3 of the

This setting is kept in memory.

Monitoring reagent level

CAUTION!

The reagent and waste liquid levels must be monitored by the user.

To ensure proper staining and to protect the stainer:



- never allow a reagent line to run dry. When the reagent liquid level is near the bottom of a reagent bottle, replace the bottle, see "Replacing a reagent bottle", page 4-12.

- never allow the waste liquid level to go above the maximum safety level. When the waste container is full, empty it: see "Emptying the waste container", page 4-13.

IMPORTANT!

Do not transfer residual reagent from a used bottle to a fresh bottle. Doing so can lead to noticeable accumulation of precipitates on the slide, particularly with the iodine and Crystal Violet stains (B & C).

Replacing a reagent bottle



Open the new bottle, record the letter on the cap and keep it for future use (e.g. long term storage).



Unscrew the cap and remove the dip tube from the empty bottle.



Insert the dip tube into the appropriate reagent bottle and screw on the ring cap.



Discard the bottle in a biohazard container.















Emptying the waste container

WEEKLY PROCESS



Disconnect the waste tubing from the full waste container.



Empty the waste container.



Throw the effluents into an appropriate biohazard bin in accordance with local regulations.



Connect the waste tubing to the empty waste container.

The instrument is ready for use.







Note:

bioMérieux recommends emptying the waste container once a week: see "Maintenance and cleaning", page 5-1.

Other settings

WARNING!

The information contained in this section is intended for customers who wish to use this equipment with applications other than those specified by bioMérieux.

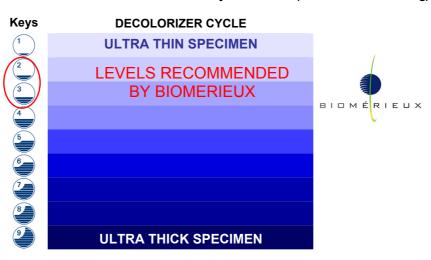
In that case, the user assumes complete responsibility for that use.

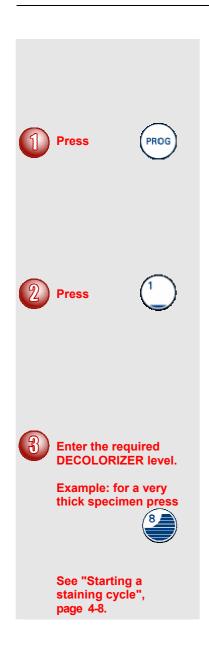
Decolorizer setting

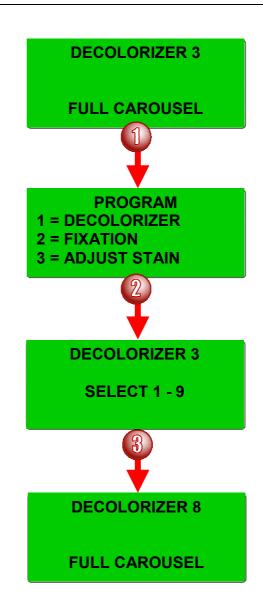
The decolorizer cycle intensity can be changed according to the type of specimens or the staining results expected.

IMPORTANT!

Levels 2 and 3 have been validated by bioMérieux (level 3: default setting).







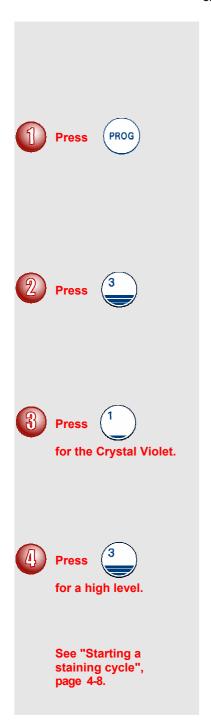
Stain adjustment

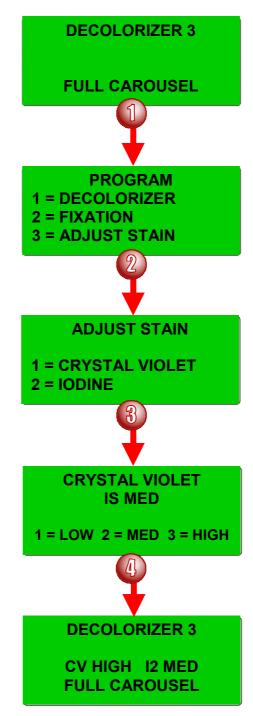
These settings can be used if the desired staining is not achieved through the decolorizer settings alone. Once you have found the decolorized setting that works, you can adjust the amount of Crystal Violet (C) and Iodine (B) according to 3 settings: Low, Default and High.

Recommended setting is Medium.

A setting of reagent C High and reagent B High will produce darker Gram-positive organisms.

A setting of reagent C Low and reagent B Low will produce lighter Gram-positive organisms.





Note: For setting the IODINE level, simply press



in step 3 instead of



5. Maintenance and cleaning



DANGER!

Reagents used in the PREVI™ Color Gram contain moderately hazardous chemicals that require care in handling. Always use appropriate safety measures including gloves and eye protection when handling reagents.







CAUTION!

Before performing any maintenance operations, remove all the slides from the carousel.

bioMérieux strongly recommends following this maintenance plan to keep the PREVI™ Color Gram in good operating condition.

One week is the maximum time between two successive staining runs. If the PREVI™ Color Gram is not used for more than one week, the long-term storage procedure must be applied (see "Long-term storage" page, 5-16).

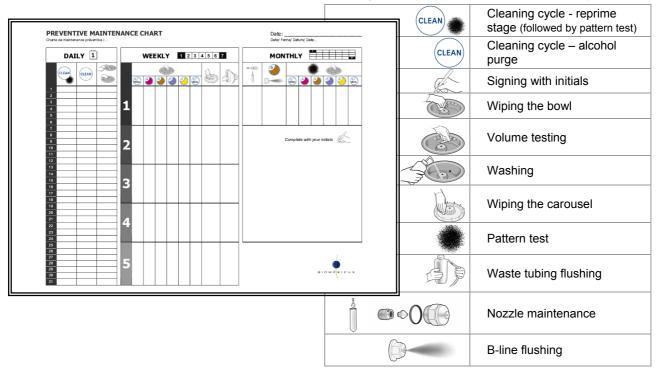
Preventive maintenance plan

The preventive maintenance chart is a support to be used:

- DAILY.
- WEEKLY,
- MONTHLY.
- YEARLY, and each time it is necessary to intervene on the instrument and its parts.

Preventive maintenance chart

Icons are used to help fill in the "Preventive maintenance chart", page 7-1. This chart must be printed monthly:



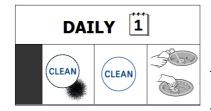
DAILY maintenance

IMPORTANT!

Check reagent levels and expiry dates.

CAUTION!

This procedure is applicable when the time between two runs exceeds 3 hours.



Before restarting a new staining run successively perform :



the CLEAN cycle: see "CLEAN reprime stage", page 4-2.

the PATTERN test: see "Pattern test", page 4-3.

After the last run:



the CLEAN cycle alcohol purge stage after the last run, see "CLEAN alcohol purge stage", page 4-10.

The instrument is on STAND BY and can be switched off.



Spray and wipe the interior of the bowl and the nozzles with ethanol 70%.



Clean the instrument lid with ethanol 70%.



Check that the maintenance procedures have been completed by following the "Preventive maintenance chart", page 7-1 and then sign with your initials.

WEEKLY maintenance





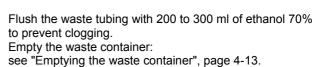
Beginning of the week

Perform the "Volume test", page 5-10.



End of the week

Wipe the carousel tray and lid using paper towel with ethanol 70%.





Check that the maintenance procedures have been completed by following the "Preventive maintenance chart", page 7-1 and then sign with your initials.

MONTHLY maintenance





Disassemble and clean all the nozzles: see "Disassembly", page 5-4.



Perform the B flushing procedure: see "B line flushing procedure", page 5-13.



Perform the Pattern test: see "Pattern test", page 4-3.



Perform the "Volume test", page 5-10. If tests are incorrect, see "Nozzle handling", page 5-4 and repeat the tests with the cleaned nozzles.



Check that the maintenance procedures have been completed by following the "Preventive maintenance chart", page 7-1 and then sign with your initials.

WARNING

WASTE DISPOSAL - Dispose of used or unused reagents as well as any other contaminated disposable materials following procedures for infectious or potentially infectious products.

It is the responsibility of each laboratory to handle waste and effluents produced according to their nature and degree of hazardousness and to treat and dispose of them (or have them treated and disposed of) in accordance with any applicable regulations.

YEARLY maintenance

Contact your bioMérieux representative.

Nozzle handling

Disassembly

The maintenance kit and the cleaning solution are required.

IMPORTANT!

If the compression screw cannot be easily loosened, use light penetrating oil and a 5/8 inch wrench to loosen the nozzle.

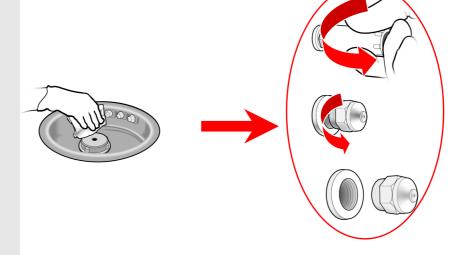


Perform the clean see "CLEAN alcohol purge stage" page 4-10.



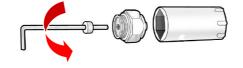


Remove the nozzle.





Disassemble the nozzle.







Remove the O-ring and discard it.

The O-ring must be changed monthly.





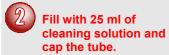
Repeat previous actions 2 to 4 for each nozzle.

Cleaning

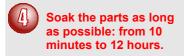


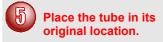
Place the nozzle parts in the 50 ml centrifuge tube position D_{F} .

Note the reagent letter on the tube.

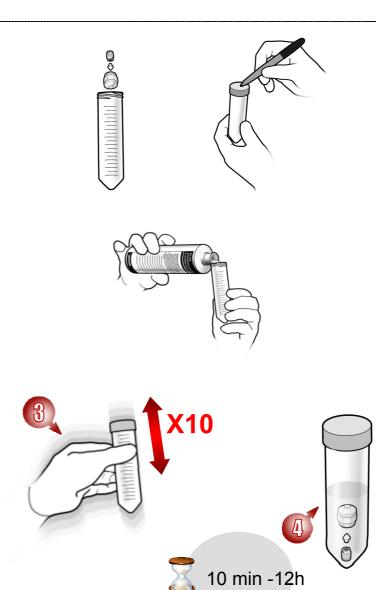


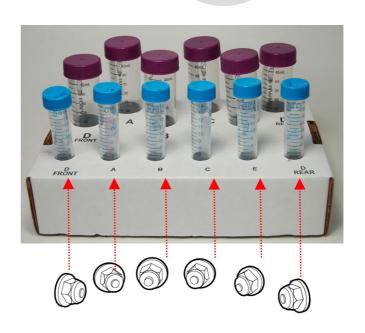












Reassembly

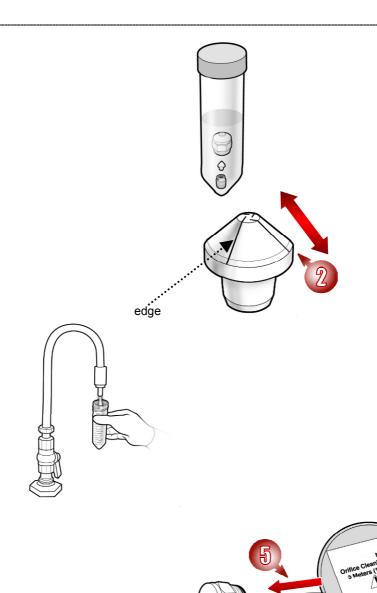


Empty the tube into the bowl with a skimmer or your thumb to prevent nozzle loss.

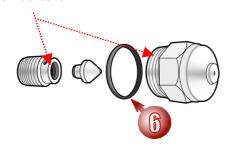
- 2
- Inspect nozzle parts.

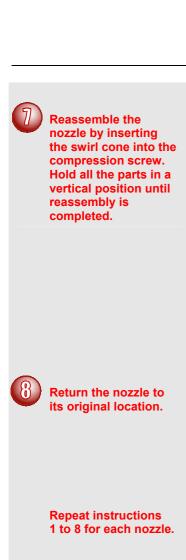
Remove any material in the swirl cone grooves by sliding a piece of paper along the edge.

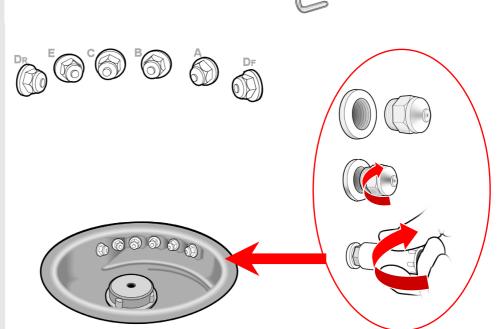
- Rinse parts in the tube with distilled water.
- Rinse with ethanol 70%.
- Push the wire through the back of the disassembled nozzle.
- Replace the O-ring and apply silicon lubricant.

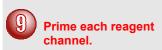


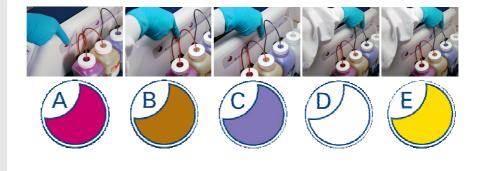












Perform pattern and volume tests before reusing the instrument.

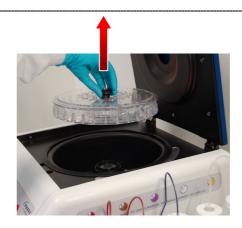


IMPORTANT! If the test is still not correct, see "Unclogging the tubing", page 5-8.

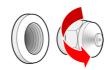
Unclogging the tubing



Remove the carousel from the stainer.

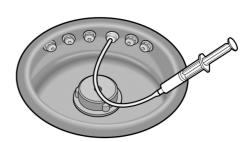


Remove the nozzle connected to the air locked pump.



Screw the nozzle adapter of the unclogging tool (included in the nozzle maintenance kit) into the nozzle holder.





Withdraw the unclogging tool plunger to create a vacuum.
Hold the plunger at midpoint to prevent it being drawn back by the vacuum.



Press the desired prime button to start the reagent pump.





Run the reagent into the tube of until the fluid runs free of bubbles.

The plunger can be withdrawn further to accept more fluid. Do not pull the plunger completely out of the barrel of the tool.





Remove the nozzle adapter tubing

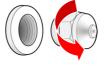
and

express the collected fluid into the stainer bowl.





Reinstall the nozzle.





Perform pattern and volume tests before reusing the instrument.



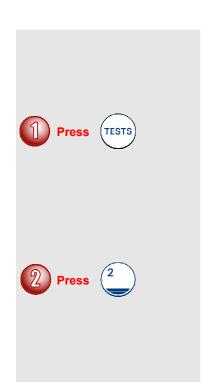


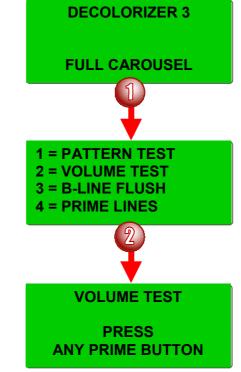
IMPORTANT!

If the test is still not correct, contact your bioMérieux representative.

Volume test

The maintenance kit is required for this test that must be performed weekly.





Hold a volume test tube (small tube) in place so that the nozzle C is covered to capture dispensed liquid.









Remove and close the tube. Record the reagent letter on the tube.



Place the tube in position C.



Repeat steps 3, 4, 5 and 6 for all the other nozzles (D_F, D_R, A, B and E).





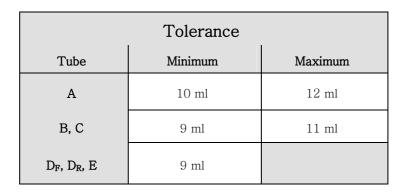
Check each tube according to the following table.

If the volume is in the tolerance range, go to point 9.

If the volume obtained is out of the tolerance range:

- too low, loosen the nozzle slightly
- too high, tighten the nozzle slightly

And repeat the test.



V

If the volume is in the tolerance range, go to point 9.

X

If the volume is still out of the tolerance range, see "Nozzle handling", page 5-4 to clean the nozzle. Repeat the tests with the cleaned nozzles.



If the volume is in the tolerance range, go to point 9.

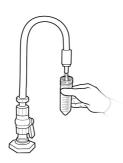


If the volume is still out of the tolerance range, contact your bioMérieux representative.



For future use:

- empty the contents of the tubes into the bowl,
- clean the tubes,
- rinse the tubes with distilled water, (waste liquid thrown in the bowl),
- put the tubes back into their original place in the maintenance box.



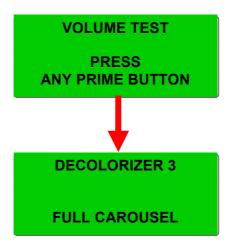






Press





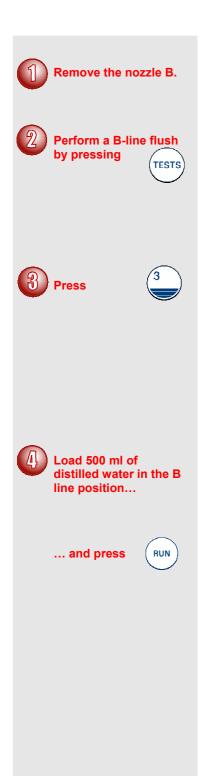
B line flushing procedure

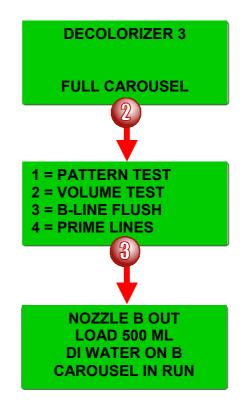
The maintenance kit is required for the following test that must be performed monthly.

B line is prone to corrosion and needs a higher level of cleaning.

IMPORTANT!

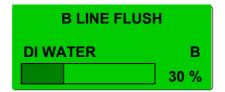
A carousel must be in place during the procedure otherwise it will generate an error and will not continue the process.







Note: pump approx. 400 ml of distilled water through the B line.





Remove the remaining distilled water.
Load 200 ml of the diluted nozzle cleaning solution in the B line position...



RUN



LOAD 200 ML LINE CLEANER ON B PRESS RUN

Note: pump approx. 100 ml of the cleaning solution through the B line.



B LINE FLUSH

59 MIN 30 SEC



Allow to sit for at least 1 hour, up to 12 hours if possible.



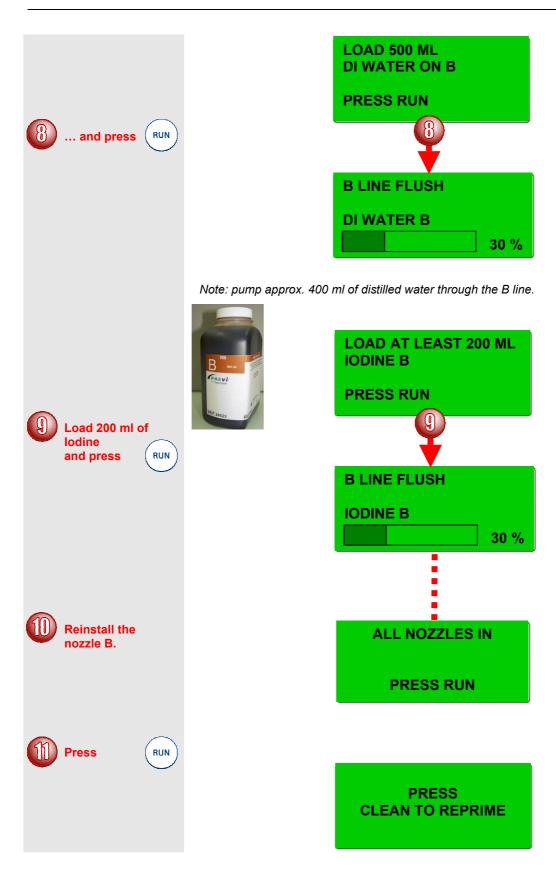
Note: in the meantime, centrifuge mode can be activated by pressing



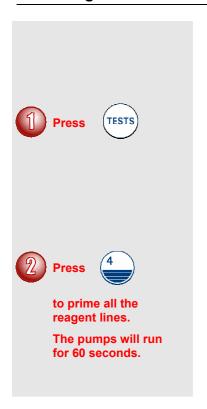


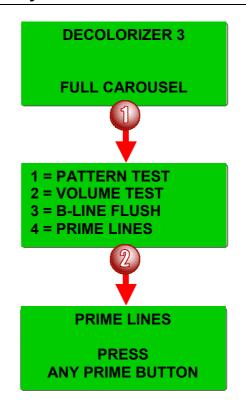
After soaking, load 500 ml of distilled water in B line position to rinse...





Priming all lines simultaneously



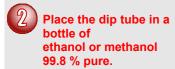


Long-term storage

If the *PREVI*TM *Color Gram* is inactive for more than a week, perform the following steps. This long-term storage procedure will prevent nozzle plugging from occurring when the instrument is ready to be used again.









Install a cap on the reagent bottle and set the bottle aside.



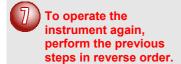
Flush at least 250 ml of ethanol or methanol through the line and spray the nozzle by priming.

Leave ethanol or methanol in the line.



Remove and clean the nozzles, see "Disassembly", page 5-4 and "Cleaning", page 5-5.









IMPORTANT! Leave flushing fluids in the reagent lines during storage.

Do not run reagent lines dry.



CAUTION! Do not subject the instrument to freezing temperatures if aqueous fluids remain in any of the reagent lines.

Serious damage may result.

Cleaning



DANGER!

Prior to cleaning, disconnect the PREVI™ Color Gram from the main power supply to avoid any risk of fire and explosion.

The cleaning procedure should be performed in a well ventilated room by authorized trained personnel wearing appropriate individual protection equipment.







Cleaning the instrument and the carousel

Clean the outside of the instrument and the carousel with a dry or moist cloth only. If very dirty, clean them with a cloth moistened with ethanol (70%) or mild detergent.

For better cleaning, leave the carousel for half a day in a container full of 10% mild detergent. Rinse under water (bioMérieux strongly recommends distilled water) then wipe dry with a clean cloth moistened with ethanol (70%).

Wipe with a lint-free cloth.

Liquid spills

If any liquid is spilled on the *PREVI*TM *Color Gram*, it should be removed immediately to avoid affecting the performance of the equipment.



DANGER!

If liquid spilled on the PREVI™ Color Gram is potentially infectious, it should be disinfected in accordance with any local applicable regulations.

CAUTION!

For disinfection solutions and procedure see "Disinfecting and/or sterilizing", page 5-19.

Note:

These decontamination procedures are for routine use only. If you are shipping the stainer to bioMérieux for repair or service, you must contact bioMérieux's representative for a current copy of the decontamination and shipping instructions before preparing and shipping the stainer. Shipping the stainer without decontaminating it according to these instructions is dangerous to service personnel and will result in significant decontamination work.

Preventing injury



If a slide breaks inside the stainer during a staining cycle, stringent precautions must be taken during clean up, especially if the instrument has been processing dangerous pathogens. Always use protective gloves, safety glasses, and forceps when removing broken glass from inside the stainer.









Glass shards can be embedded in the walls of the stainer bowl. **These can cause serious cuts and pose a danger of infection**. Always remove these shards with a scraper before attempting to remove loose glass.

Use a vacuum or adhesive tape to pick up loose glass inside the stainer bowl.

Disinfecting and/or sterilizing

All parts of the **PREVI™ color Gram** that came into contact with biological samples, patient samples, positive control samples or hazardous material must be treated as potentially infectious areas.



DANGER!

Reagents used with the PREVI™ Color Gram contain moderately hazardous chemicals that require care in handling. Always use appropriate safety measures including gloves and eye protection when handling reagents.







The disinfection procedure should be performed in a well-ventilated room by authorized trained personnel wearing appropriate individual protection equipment.

it is very important to thoroughly disinfect the PREVI™ Color Gram before removing it from the laboratory or before any technical service is performed on it.

This procedure may not be effective against prions.

Prior to cleaning, disconnect the PREVI™ Color Gram from the main power supply to avoid any risk of fire and explosion.

CAUTION!

Do not flood the bowl by overloading the drain.

Never load chipped or cracked slides into the instrument. Failure to use slides in good condition can lead to breakage during the cycle.

Make certain there are no small ferrous metal objects in the bowl. These can be attracted to the magnets on the bottom of the rotor and cause damage if spun free of the magnets during spinning of the rotor.

IMPORTANT!

Never allow fluid to rise above the base of the drive hub.

Do not spray fluids near openings in the stainer housing that will allow fluid into the instrument interior. This may cause severe damage to the instrument.

WARNING!

The disinfection procedure and the disinfectants should comply with the local applicable regulations.

Under normal clinical use the *PREVI*™ *Color Gram* poses very little risk of biological infection to laboratory workers.

Before the *PREVI™ Color Gram* is returned to bioMérieux, all outer surfaces must be disinfected. A disinfection declaration must be completed by the operating authority, otherwise the *PREVI™ Color Gram* may not be accepted by the distributor or service center or customs authorities may hold it.

Disinfection solutions

The outer surfaces of the *PREVI™ Color Gram* should be disinfected using a surface disinfection solution such as:

- ethanol 70%
- mild detergent
- bleach solution
- for sporicidal disinfection, use a 2% alkaline activated glutaraldehyde solution (allow the solution to react for 10 hours).

Disinfection procedure



Prepare a suitable container for all disposables.

Mask the lid latch and locking pin holes with waterproof tape to protect the stainer interior.



Place the stainer in a biological safety hood or well-ventilated area.



Spray the inner bowl and inner lid with a disinfection solution.



Repeat the spray treatment every 2 or 3 minutes.

Leave the solution on surfaces for approximately 20 minutes.

Do not allow cleaning solutions to dry on the stainer surfaces.



Rinse the inner bowl and lid thoroughly with water (bioMérieux strongly recommends distilled water).





IMPORTANT!

For sporicidal disinfection, allow the solution to react for 10 hours.







Wipe the exterior surfaces.
Do not flood the display panel with excessive moisture.
Any moisture that seeps through could damage the internal electronics.



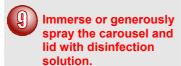
Repeat wipe down every 2 or 3 minutes for about 10 minutes total.



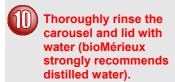
Remove the decontamination solution by thoroughly wiping surfaces with a cloth soaked in water.

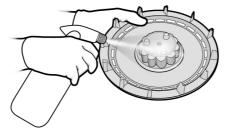


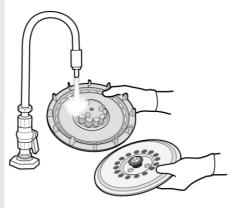




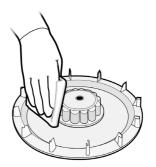












Instrument shipment

WARNING!

Before the PREVI™ Color Gram is returned to bioMérieux, it must at least be disinfected.

A disinfection declaration must be completed by the operating authority, see "Disinfection declaration", page 5-22.

If a disinfection declaration is not supplied, the PREVI™ Color Gram may not be accepted by the distributor or service center or customs authorities may hold it.

Ship your instrument in a container comparable to its original packaging. Shipping conditions: Temperature 0 to 40°C, Humidity <80% non condensing.

Disinfection declaration

The following disinfection declaration MUST be printed and completed by the operating authority and attached to the top of the package in which the *PREVI™ Color Gram* is returned, before being sent to bioMérieux.

- Disinfection declaration -

	m in this package has been disinfected to remove or
	atient samples or hazardous material, which could be never been exposed to any biohazardous material.
uangerous to personner, or that it has i	iever been exposed to any bionazardous material.
Contact person:	
Company - institution:	
Function:	
Phone - Fax:	
E-mail:	
Date of disinfection:	
Date, name:	
Signature:	

Fuse replacement



DANGER!

To prevent the risk of fire, the main fuses should only be replaced with fuses of the same type and rating.

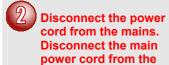
If fuse failure recurs, please call your bioMérieux representative.

CAUTION!

Fuse failure may indicate a serious internal problem. For continued protection, replace only with fuses of the type and rating indicated on the rear panel of the stainer.

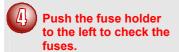


Put the power switch in position **O**.

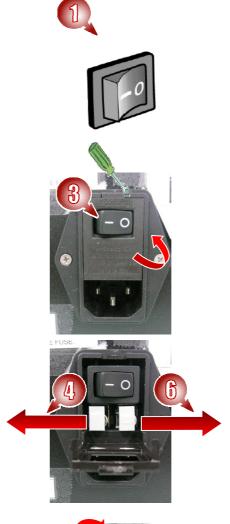


socket.

Open the cover with a small screwdriver.



- Replace fuses if necessary.
- Push the fuse holder to the right.
- Close the cover.
- Reconnect the power cord (socket and mains) and switch on the instrument.





6. Troubleshooting

The following section provides suggestions to help you quickly solve routine problems that might be encountered with the $PREVI^{TM}$ Color Gram. These solutions are indexed to additional information found throughout this manual.

Because more difficult problems may require detailed technical service, institutions with qualified service personnel should obtain and refer to the *PREVI*TM *Color Gram* Service Manual. Otherwise you should contact your bioMérieux representative for assistance.

The following table gives a brief description of the error messages and the troubleshooting actions.

IMPORTANT!

If the recovery procedure does not work, please contact your bioMérieux representative.

Error messages and Troubleshooting Table

Theme	Description and Error Messages	Recovery Procedure	
POWER	There is no power to the stainer when the power switch is turned	Check the electrical outlet and the power cord connection.	
	ON.	Check the fuses by disconnecting the power cord from the power entry module, then opening the fuse door.	
		For continued protection, replace only with fuses of the type and rating indicated on the rear panel of the stainer.	
		CAUTION! Fuse failure may indicate a serious internal problem.	
DISPLAY	Strange information shown on the display, and/or erratic stainer operation.	 Switch the stainer OFF, Wait 10 to 20 seconds, Switch power ON again. 	
	(The stainer does not begin a cycle when you press RUN).	If this works temporarily but the problem recurs, install a computer-type surge suppressor to protect the instrument from power line transients. If possible, connect the stainer to a power circuit that is not shared by centrifuges, refrigerators, air conditioners, or other motorized equipment.	
	The display is blank when the POWER light is lit.	Switch the stainer OFF, Wait 10 to 20 seconds,	
		3. Switch power ON again.	
		If the display is still blank, there may be an internal problem. If the problem persists, please contact your bioMérieux representative.	
	If the display shows	Verify that the lid is fully closed, and the latch is	
LID NOT SHUT		engaged. If the Lid Not Shut indication remains, there may be an internal problem. If the problem persists, please contact you bioMérieux representative.	

Theme	Description and Error Messages	Recovery Procedure
	If the display shows WRONG ROTOR a few seconds:	After you press RUN, make sure the slide carousel is properly loaded on the drive hub.
	WRONG ROTOR	In staining mode, the instrument automatically detects whether the staining carousel is present before proceeding.
		In cytocentrifuge mode, the instrument will stop if it senses the staining carousel.
	(The stainer does not begin a cycle when you press RUN.)	After you verify that the carousel is correctly loaded, press RUN. If the display still shows WRONG ROTOR, there may be an internal problem. Check carousel magnets. If the problem persists, please contact your bioMérieux representative.
PRIMING	A reagent line will not prime, even after following the procedures.	Press the priming button while listening carefully for the sound of the pump operating. If you cannot hear the pump, there may be an internal problem, please contact your bioMérieux representative.
STAINING	Stainer bowl fills with reagent after use.	A small puddle of stain around the drain opening at the rear of the bowl or a few drops of stain around the bottom of the bowl is not unusual and will not cause a problem.
		If the bowl is filling with a large quantity of stain, check the external drain tube. Make sure the drain tube is properly connected to the drain port on the stainer's rear panel. The tubing must run continuously down toward your lab drain or waste container, with no loops, rises, or obstructions. Make sure the end of the tubing is not submerged in liquid. This can prevent proper drainage.
		If you are using a waste container, make sure the container is vented to allow air to be displaced by the spent stain. Check the drain tube for blockage or foreign material. If the problem persists, please contact your bioMérieux representative.
	If the display shows:	Check the stainer bowl to make sure there is no foreign material interfering with the rotation of the drive hub and carousel.
	DRIVE PROBLEM	Turn the hub or carousel by hand; it should turn freely. 1. Switch the stainer OFF,
		2. Wait 10 to 20 seconds,
	(The stainer does not begin a cycle when you press RUN).	3. Switch power ON again and try again.
	Cycle when you press itoly).	Continued DRIVE PROBLEM display indicates an internal problem, please contact your bioMérieux representative.

Theme	Description and Error Messages	Recovery Procedure
	If the display shows:	Make certain the rotor is balanced and that the carousel is seated correctly on the hub.
	ROTOR IMBALANCE	Verify keyboard operation by observing the display while entering slide number settings. The settings should appear on the display as you press the intensity keys.
	(The stainer does not begin a cycle when you press RUN).	 Switch the stainer OFF, Wait 10 to 20 seconds, Switch power ON again and try again. If the problem persists, please contact your bioMérieux representative.
STAINING	Stain is leaking onto the lab bench.	Check all external reagent lines for visible signs of cracks or loose fittings. Make sure the drain outlet (inside the stainer bowl) is not blocked by any foreign material. Make sure the drain tube is securely attached to the drain port and that the tubing is not cracked or deformed. If the problem persists, please contact your bioMérieux representative.
STAINING	The stainer fails to spray reagent during a staining cycle and/or continues to run after the cycle should be complete.	To allow programmed staining of partial loads, the stainer monitors the position of the carousel as it rotates in the bowl. Stain is sprayed only in the correct position. This causes the actual cycle time to vary, depending on the position of the carousel at the beginning of the cycle. This is normal stainer operation. However, if the cycle continues for an abnormally long period, or if the bar graph and percentage complete icon do not change after 1 minute, it may indicate an electronic problem or an internal problem. To determine this, press the STOP button. If the cycle stops: this indicates a problem with the carousel position sensor. If the cycle continues: this indicates an electronic problem. 1. Switch the stainer OFF, 2. Wait 10 to 20 seconds, 3. Switch power ON again to reset the instrument. If the problem persists, please contact your bioMérieux representative.

Theme	Description and Error Messages	Recovery Procedure
STAINING	Abnormal staining on entire	Check reagent levels in bottles.
	surface of all slides.	Make sure the external reagent dip tubes are securely attached to each bottle.
		Verify that each reagent pump is primed by opening the lid and pressing the manual prime button. The nozzle should immediately spray a fine mist of reagent. There should be no sputtering or hissing sounds, which indicate the presence of air in the reagent lines.
		Watch the external reagent pickup lines to see if there are any air bubbles present. Air bubbles indicate inadequate priming or possibly an air or reagent leak in the system. Air bubbles in any reagent line will likely cause poor staining.
		Check nozzle performance using the Spray Pattern and Volume tests (see "Pattern and volume testing", page 3-6). If necessary, clean nozzle(s).
		If you are staining a full carousel (7 or more slides for the 12-slide carousel or 17 or more for the 30-slide carousel), make certain you have not programmed the stainer for fewer slides.
		If you program the stainer for a partial load, be sure to load the slides in the correct positions as indicated by the markings on the carousel.
		If the problem persists, please contact your bioMérieux representative.
	Abnormal staining on entire surface of some slides, while other slides from the same carousel appear normal.	Make certain that both position magnets are still attached to the bottom of the carousel. Make certain you have not programmed the stainer for fewer slides than you have loaded.
		If you program the stainer for a partial load, be sure to load the slides in the correct positions as indicated by the markings on the carousel.
		Verify that each reagent pump is primed by opening the lid and pressing the manual prime button. The nozzle should immediately spray a fine mist of reagent. There should be no sputtering or hissing sounds to indicate the presence of air in the reagent lines.
		If the problem persists, please contact your bioMérieux representative.
	Streaks or bands of discoloration on one or more slides.	Check the level of the Reagent D bottle. Check Reagent D spray volume according to tolerance range.
		Check nozzle spray pattern according to the procedures (see "Pattern and volume testing", page 3-6). This type of discoloration is usually caused by a piece of debris or reagent precipitate clogging the spray nozzle orifice.
		Clean any nozzle that exhibits a poor spray pattern.
		If the problem persists, please contact your bioMérieux representative.

Theme	Description and Error Messages	Recovery Procedure	
	Specimens are washing off slides.	If you are heat fixing slides: Make sure you are using adequate heat. Try fixing some slides with alcohol in addition to heat, to verify the fixation step.	
		Try to make your smears as thin as possible for a given specimen, to minimize fixation problems.	
	Be sure to use clean, premium quality slide		
		If you are using the instrument's alcohol fixation function, make sure the fixation function is activated (the display reads FIX normal or fix HIGH). If using normal fixation, switch to high to apply more alcohol.	
		Check the alcohol (Reagent E) level in the bottle.	
		Check the alcohol (Reagent E) nozzle spray pattern and spray volume.	
		If the problem persists, please contact your bioMérieux representative.	

7. Preventive maintenance chart

